IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

JULIE TUTTLE, individually and on behalf of the ESTATE OF MICHAEL PAUL TUTTLE, et al.,	:	**CASE NO. 1:20-cv-04744**
Plaintiff,	:	**JUDGE LEIGH MARTIN MAY**
v.	:	
DEXCOM, INC., et al.,	:	
Defendant.	:	

DEXCOM, INC.'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS

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I. INTRODUCTION

This action allegedly arises from decedent Michael Paul Tuttle's prescribed use of a Dexcom G6 Continuous Glucose Monitoring System ("G6"). The United States Food and Drug Administration approved multiple generations of Dexcom's continuous glucose monitoring systems through the Premarket Approval ("PMA") process, and cleared the Dexcom G6 through the De Novo process for novel Class II medical devices.[1] Plaintiff Julie Tuttle alleges that Mr. Tuttle sustained personal injuries as a result of Dexcom's alleged violations of state-law duties. Those purported state-law duties are inconsistent with Dexcom's federal obligations and, therefore, plaintiff's claims are preempted.

Notwithstanding that plaintiff's claims are preempted, they also are insufficiently pled under Federal Rule of Civil Procedure 8. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). While plaintiff baldly asserts that "[a]mongst other defects the G6 App could stop alerting the user to hypoglycemia or stop receiving glucose information from the G6 System" (Complt., ¶¶ 40-41), a concern that is squarely addressed in the labeling and directly contradicts plaintiff's Complaint, plaintiff's threadbare allegations fail to identify

[1] The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. *See* https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request.

any meaningful defect with the G6, which is fatal to her claims. Plaintiff also demands punitive damages without any basis to support the demand.

Plaintiff fails to assert a viable claim and the Complaint should be dismissed.

II. BACKGROUND

A. ALLEGATIONS IN THE COMPLAINT

Plaintiff filed her Complaint on October 21, 2020, in Gwinnett County. (*See* Complt.) Dexcom removed the case on November 20, 2020.

Without reference to decedent's care and treatment, plaintiff alleges that "[o]n May 1, 2019, Michael Tuttle's doctor prescribed [Mr. Tuttle] the G6 System for the purpose of blood glucose testing, diabetes treatment decisions, and detecting episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments." (Complt., ¶ 21 (parroting language from the G6 label, not decedent's medical records.) Before using the G6, Mr. Tuttle used prior versions of the device. (*Id.*, ¶ 22.) Further "[d]uring the relevant time, Michael Tuttle used the G6 App as the display device for the G6 System." (*Id.*, ¶ 25.)

According to plaintiff, on November 9, 2019, Mr. Tuttle's "G6 App stopped alerting him to hypoglycemia and/or stopped receiving glucose information from the G6 System," and "he had a severe occurrence of hypoglycemia (low blood sugar)." (*Id.*, ¶¶ 29, 30.) Plaintiff reports that she "found [Mr. Tuttle] unresponsive and lying in bed" on November 10, 2019. (*Id.*, ¶ 32.)

Plaintiff's Complaint has four counts: (1) Strict Liability; (2) Negligence; (3) Breach of Warranty; and (4) Alleged Punitive Damages. (*Id*., ¶ 40.) The allegations, however, are merely unsupported assertions that the G6 was "designed, developed, manufactured, tested, supplied, promoted, distributed and/or sold by Dexcom in a condition which was defective and unreasonably dangerous and which caused injuries to Mr. Tuttle" because "the G6 App could stop alerting the user to hypoglycemia or stop receiving glucose information from the G6 System." (*Id*., ¶¶ 40, 43.) Plaintiff purports to assert a breach of warranty claim, but fails to identify any express or implied warranty Dexcom allegedly made to Mr. Tuttle (or anyone else). (*Id*., ¶¶ 45-50.)

B. FDA REGULATION OF DEXCOM'S CGMSS

1. The De Novo Classification Process Provides "Reasonable Assurance of Safety and Effectiveness"

The Medical Device Amendments ("MDA") to the Food Drug & Cosmetic Act ("FDCA") "impose[s] a regime of detailed federal oversight" over medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Depending on the potential risks posed, devices are classified as Class I, II, or III. Class III devices, like preceding generations of Dexcom's CGMS, are those used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or which "present[] a potential unreasonable risk of illness or injury." *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)). Class II also includes

devices used "in supporting or sustaining human life," but for which general controls alone are insufficient to provide reasonable assurance of the device's safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance. *See* 21 U.S.C. § 360c(a)(1)(B).

The majority of Class II devices receive clearance through the 510(k) process by demonstrating substantial equivalence to another legally marketed device. A small number of devices, like the G6, however, are cleared through FDA's De Novo process. *See* 21 U.S.C. § 360c(a)(1)(B). The De Novo process is an alternate pathway for novel Class II devices where general (such as labeling, device listing, registration requirements, quality systems, good manufacturing practices, post-market surveillance, data requirements, and performance standards) and special controls (device-specific requirements such as performance standards, postmarket surveillance, patient registries, special labeling requirements, premarket data requirements, and guidelines) assure safety and effectiveness for the intended use, but for which no predicate device has been legally marketed.[2] *Id.* (emphasis added.)

The traditional 510(k) pathway is based on equivalence to a predicate device, but devices approved through the De Novo process are evaluated for "safety and effectiveness," not equivalence. *See* 21 U.S.C. §360c(f)(2)(A)(v) (emphasis added)

[2] A "predicate device" is a device legally marketed before May 28, 1976, for which premarket approval is not required, or a device reclassified from Class III to Class II or I, or a device which has been found substantially equivalent through the 510(k) process. 21 C.F.R. § 807.92(a)(3).

("The person submitting the request for classification…shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls…to provide reasonable assurance of safety and effectiveness.").[3]

2. FDA Evaluated the Dexcom G6 Through the De Novo Device Classification Process

Plaintiff alleges that Mr. Tuttle "used prior versions of Dexcom's glucose monitoring systems." (Complt., ¶ 22.) Like prior versions, the G6 is a prescription medical device indicated for use in the diabetes management.[4] Interpretation of the G6 System results should be based on the glucose trends and several sequential readings over time. (*Id.*) It consists of three main components: a sensor, a transmitter, and a display device. (*Id.*) The user can view glucose data on the Dexcom receiver or may use the G6 App (i.e., a mobile medical application) to view data on

[3] *See also* FDA 2017 Guidance De Novo Classification Process (Evaluation of Automatic Class III Designation) ("If . . . general and special controls are insufficient to provide reasonable assurance of safety and effectiveness or the information and/or the data provided in the De Novo request are insufficient to determine whether general controls or general and special controls can provide a reasonable assurance of safety and effectiveness, we will decline the De Novo request and you may not legally market the device."). Available at https://www.fda.gov/media/72674/download.

[4] *See* FDA Decision Summary for the Dexcom G6 ("Decision Summary"), available at https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170088.pdf, Ex. A. This Court may take judicial notice of the regulatory history for Dexcom's devices because FDA's public website is maintained in the normal course of FDA's business and reflects final agency action. *See* Fed. R. Evid. 201(b); *see also Universal Express, Inc. v. U.S. Sec. & Exch. Comm'n*, 177 Fed. Appx. 52, 53 (11th Cir. 2006) ("Public records are among the permissible facts that a district court may consider."); *Henderson v. Sun Pharm. Indus., Ltd.*, 809 F. Supp. 2d 1373, 1379 n. 4 (N.D. Ga. 2011) ("The Court is permitted to take judicial notice of documents made publicly available by a government entity."); *Thomas v. Alcon Labs*., 116 F. Supp. 3d 1361, 1365 (N.D. Ga. 2013) ("[C]ourts have taken judicial notice of documents from the FDA, a government entity, when ruling on a motion to dismiss.").

compatible personal mobile equipment, such as an I-phone, (as decedent allegedly did here), or on both simultaneously. (*Id.*) The G6 has an extensive regulatory history, and is unlike devices cleared through the traditional 510(k) process.

In 2012, FDA approved the original version of the device, the Dexcom G4 Platinum CGMS, through the PMA process.[5] That process requires the applicant to submit detailed information regarding the safety and efficacy of the device, which FDA spends an average of 1,200 hours reviewing. *Riegel*, 552 U.S. at 317-18. After a thorough risk-benefit analysis, FDA "grants premarket approval only if it finds 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (citing 21 U.S.C. § 360e(d)). The PMA process involves a thorough and ongoing risk-benefit analysis, weighing the potential benefits of the device against its potential risks. Later versions of Dexcom CGM systems, including the Dexcom G5 Mobile CGMS, continued to be approved through PMA supplements to the original PMA.

On March 27, 2018, and in light of this history, FDA authorized Dexcom to market the Dexcom G6 through the De Novo device classification process.[6] The Dexcom G6 may be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin

[5] *See* PMA Database Listing for P120005, available at https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005A.pdf, Ex. B.

[6] *See* Dexcom G6 De Novo Request for Classification Approval Letter, available at https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170088.pdf, Ex. C.

dosing systems, insulin pumps, blood glucose meters, or other electronic devices used for diabetes management. (*See* FDA Dexcom G6 Decision Summary, Ex. A.) In order to grant Dexcom's De Novo application, FDA evaluated data from two G6 clinical studies "to support the accuracy performance of the device," as well as the design, manufacturing, and labeling of the G6 for safety and effectiveness. (*Id.*)

FDA imposed device-specific federal requirements "intended to provide reasonable assurance of the safety and effectiveness of the device for intended users, adequate controls for secure and reliable inter-device communication, manufacturing controls to assure all released devices maintain adequate performance to mitigate the risks identified above, and adequate transparency to allow the community to understand expected sensor performance." (*Id.* (emphasis added).) The multiple special controls applicable to the G6, as relevant to plaintiff's claims, include design, manufacture, testing, and labeling requirements:

(1) Design verification and validation, which includes "robust clinical data demonstrating the accuracy of the device in the intended use."

(vii) Data must demonstrate that throughout the claimed sensor life, the device does not allow clinically significant gaps in sensor data availability that would prevent any digitally connected devices from achieving their intended use.

(2) Design verification and validation must include a detailed strategy to ensure secure and reliable means of iCGM data transmission to provide real-time glucose readings at clinically meaningful time intervals to devices intended to receive the iCGM glucose data.

(3) Design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the performance specifications as defined in paragraphs (1) and (2) of this section.

(4) The device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances that are reasonably present in the intended use population, including but not limited to endogenous substances and metabolites, foods, dietary supplements, and medications.

(5) The device must include appropriate measures to ensure that disposable sensors cannot be used beyond its claimed sensor wear period.

(6) Design verification and validation must include results obtained through a usability study that demonstrates that the intended user can use the device safely and obtain the expected glucose measurement accuracy.

(7) The labeling must include a separate description of certain sensor performance data observed in the clinical study.

(*Id.*, 40-42.)[7] Those special controls are set forth in the FDA's G6 approval summary, and are "device-specific" special controls FDA determined necessary to provide reasonable assurance of the safety and effectiveness of the G6. FDA also scrutinized the mobile app that worked with the G6.[8]

3. The Dexcom G6 User Guide Warned About the Potential for Connectivity-Related Issues

Plaintiff's allegations are directly contradicted by the G6 label when it was prescribed to decedent. And every G6 includes express warnings about plaintiff's alleged labeling criticism. For example, the 354-page User Guide includes specific

[7] The special controls in the Dexcom G6 Decision Summary will appear in 21 C.F.R. § 862.1355, though FDA has not published that section yet. *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=682 (product classification as Integrated Continuous Glucose Monitoring System, Factory Calibrated, Regulation Number 862.1355). The Decision Summary identifies the applicable special controls, which are effective from the approval date. *See* De Novo Classification Process (Evaluation of Automatic Class III Designation), at 5.

[8] FDA has made it clear that it regulates software functions that use an attachment to the mobile platform to measure blood glucose levels as medical devices. (*See* FDA 2019 Guidance, Policy for Device Software Functions and Mobile Medical Applications, including Appx. C at 25, Ex. E.

warnings about the potential for "signal loss" and "[d]isplay device and transmitter not connecting." (*See* G6 User Guide, 36, 55, 145 176, 231.) In instances of signal loss, users are advised to "Use meter. No glucose alarm/alerts or G6 readings until fixed." (*Id.*, at 231.)[9] Dexcom identifies and warns about numerous scenarios in which a user may not receive alarms/alerts:

> Not Getting Alarm/Alerts
>
> If you aren't getting your alarm/alerts, you could have severe low or high glucose without knowing it. Check your display device:
>
> - Battery charged: If the display device battery is dead, you won't get G6 readings or alarm/alerts.
> - App on: Keep the app on so you get G6 readings or alarm/alerts.
> - Alerts on: Leave the alert function on to get alarm/alerts.
> - Volume up: Keep the volume loud enough to hear your alarm/alerts.
> - Speaker and vibrations work: If the speaker or vibrations aren't working, you won't hear or feel your alarm/alerts.
> - In range: Keep your display device no more than 20 feet from your transmitter, with no obstacles between them. They have to be that close to communicate. If they aren't in range, you won't get G6 readings or alarm/alerts.
> - No System errors: If you get a system error – such as No Readings, Sensor Error, or Signal Loss – you won't get G6 readings or alarm/alerts.

[9] The Court is permitted to consider the User Guide in conjunction with Dexcom's 12(b)(6) motion because plaintiff refers to the G6 labeling. (*See* Complt., ¶¶ 40, 43; *see also Maxcess, Inc. v. Lucent Techs., Inc.*, 433 F.3d 1337, 1340 n.3 (11th Cir. 2005) ("[A] document outside the four corners of the complaint may still be considered if it is central to the plaintiff's claims and is undisputed in terms of authenticity."); *In re Mirena IUD Prods. Liab. Litig.*, 29 F. Supp. 345, 350 (S.D.N.Y. 2014) (considering, in conjunction with a Rule 12(b)(6) motion, warning labels for an intrauterine device that were in place at the time of the plaintiff's use of the product because the warning labels were referred to in the complaint).

- During warmup and after session ends: You won't get alarm/alerts or G6 readings during the 2-hour warmup or after a sensor session ends.

(*Id.*, at 35-36.) (Ch. 3 Risks and Benefits); *see also* 19-34 (Ch. 2 Indications for Use and Safety Statements); 133-171 (Ch. 10 Alarm and Alerts); and 225-259 (Ch.14 Troubleshooting).) Dexcom also includes data related to device performance that explicitly identifies the frequency and duration of gaps in sensor data, and of true, false, missed, and correct alert rates, *inter alia*. (*Id.* at 293 *et seq.* (Device Performance Characteristics).)

4. FDA Guidance Further Underscores FDA's Close Oversight Over the Dexcom G6

FDA issued extensive guidance for device software functions and medical mobile applications "to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or 'mobile apps') or on general-purpose computing platforms." (FDA 2019 Guidance, Ex. E.) Specifically, FDA indicated its intent to apply its regulatory oversight to software functions that are medical devices, such as the G6 App. (*Id.* at 10.) FDA explained that "[m]anufacturers of device software functions are subject to the requirements described in the applicable device classification regulation…[and] are required to follow associated controls established by the regulation." (*Id.*, at 14.)

FDA specifically found that the benefits of the G6 outweighed any potential risk of the "inability to make appropriate treatment decisions when glucose values are unavailable due to sensor signal drop-out or loss of communication with digitally connected devices." (*See* Decision Summary, Ex. A.) FDA further found that special controls (l)(vii), (2), (3), (6), and (7) are device-specific controls that mandate the design, manufacturing, and labeling of the G6. Those requirements directly relate to the alleged defects upon which plaintiff attempts to base her claims. (*Id.*, at 38.)

III. LAW AND ARGUMENT

A. PLAINTIFF'S CLAIMS ARE EXPRESSLY PREEMPTED BY FEDERAL LAW

1. The MDA's Preemption Clause Preempts Plaintiff's Claims

The MDA creates the exclusive federal regulatory framework for ensuring the safety and effectiveness of medical devices, like the G6. *See* 21 U.S.C. § 360k(a). The MDA "impose[s] a regime of detailed federal oversight" on medical device manufacturers. *Riegel*, 552 U.S. at 316. To achieve its goal, Congress enacted legislation designed to protect device manufacturers from differing state requirements. That protection is embodied in 21 U.S.C. § 360k(a), an express preemption provision prohibiting state laws that are "different from, or in addition to" FDA's requirements. The express preemption clause could not be clearer:

> [N]o State…may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device….

21 U.S.C. § 360k(a). A two-prong test is used to determine if plaintiff's claims are expressly preempted. *Riegel*, 552 U.S. at 321-22. First, the Court must "determine whether the Federal Government has established requirements applicable to" the device. *Id*. Second, if it has, the Court must decide whether plaintiff's claims "are based upon [state law] requirements with respect to [the device] that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id*. at 322 (quoting 21 U.S.C. § 360k(a)). Both requirements are met here.

2. Plaintiff's Claims Are Expressly Preempted

The first prong – "federal requirements"– is satisfied because the G6 is subject to "special controls" that specifically apply to the design, testing, manufacture, and labeling of the device. *See* 21 U.S.C. §360c(a)(1)(B), §360k(a) and 21 C.F.R. §808.1(d), §862.1355.[10] "Special control documents may provide specific requirements that support a conclusion of preemption of state law claims if they

[10] In *Medtronic, Inc. v. Lohr*, the Supreme Court held that the 510(k) process, as it existed when the device at issue was cleared in 1982, did not satisfy the first step, as 510(k) did not impose device-specific federal requirements on the *Lohr* device. 518 U.S. 470, 503 (1996). However, in 1990, Congress overhauled the 510(k) process in the Safe Medical Devices Act ("SMDA") and gave FDA broad new powers to require submission of data specifically related to "safety and effectiveness" to confirm that newly-cleared devices were safe and effective. The SMDA authorized FDA to impose "special controls" that provide reasonable assurance of the safety and effectiveness of some devices. 21 C.F.R. §860.3. *Lohr* also declared that "[t]he 510(k) process is focused on equivalence, not safety." *Id.* at 493 (emphasis original). That cannot be the case today with De Novo devices, such as the G6, because by definition there is no equivalence determination made. Indeed, FDA "may decline to undertake a classification request submitted under clause (ii) if [it] identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence." 21 U.S.C. §§360c(f)(2)(iv).

show the federal government 'has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.'" *Kelsey v. Alcon Labs., Inc.*, 2019 WL 1884225, at *9 (D. Utah, Salt Lake Cnty., Apr. 22, 2019); *see also Degelmannn v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 841 (9th Cir. 2011), vacated, 699 F.3d 1103 (9th Cir. 2012) ("The fact that lens solution is a Class II device that has come to market via the §510(k) process, as opposed to the PMA process, does not necessarily determine whether it is subject to federal 'requirements' for the purpose of §360k.").[11]

With respect to the G6, FDA did exactly that. In approving the G6 through the De Novo review process, FDA "established specific counterpart regulations or other specific requirements for the design, manufacturing, and/or labeling" of the product. *See Kelsey*, 2019 WL 1884225, at *10.

The second prong also is satisfied. As explained further below, plaintiff's claims are based on the erroneous contention that the Dexcom G6 was unsafe and should have been designed, manufactured, or labeled pursuant to different or

[11] *Degelmann* was vacated after the parties settled and voluntarily dismissed the appeal; however, the Ninth Circuit's analysis remains instructive.

additional requirements under state tort law, notwithstanding the device-specific requirements imposed by FDA. (*See, e.g.*, Complt., ¶¶ 40, 43, 46.)

a. Plaintiff's Design Defect Claims Are Preempted

Plaintiff's alleged design defect claim is based on the vague allegation that "[t]he G6 System and G6 App were designed…in a condition which was defective and unreasonably dangerous" because "the G6 App could stop alerting the user. . ." Where, as here, FDA has imposed special controls and "forbids a manufacturer from making changes in the design specifications, manufacturing processes, labeling, or any other attribute that could significantly affect the safety or effectiveness of the [device] without FDA review, comment, and permission," plaintiff's claims are preempted. *Kelsey*, 2019 WL 1884225, at *10 (holding "plaintiff's defective design and manufacture claims – whether framed as strict liability, negligence, or breach of warranty – [] preempted because the Guidance sets forth 'requirements' for the [device's] design and manufacture that are directed to safety and efficacy."). Plaintiff cannot maintain her alleged design defect claims in light of the pointed applicable federal requirements, both in terms of special controls and Guidance, that preclude any alternate design for the device.

b. Plaintiff's Failure-to-Warn Claims Are Preempted

In Counts I and II, plaintiff asserts that "Dexcom did not sufficiently warn the user" that "the G6 App could stop alerting the user to hypoglycemia or stop receiving

glucose information from the G6 System." (Complt., ¶¶ 40, 43.) That claim cannot proceed because FDA imposed special controls regarding G6 labeling that relate to the risk upon which plaintiff's failure-to-warn claims are based. Plaintiff's assertion that Dexcom "did not sufficiently warn the user" is "different from, or in addition to" the federal requirements FDA imposed, and is preempted. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 323.

Plaintiff's lack of meaningful allegations regarding how the Dexcom G6 labeling was deficient or what other labeling should have been included is telling. Not only did FDA determine that "[t]he [Dexcom G6] labeling is sufficient and satisfies the requirements of 21 CFR Parts 801 and 809, and the special controls for this type of device," but also it issued special controls to warn of the possibility of "sensor signal drop-out or loss of communication with digitally connected devices." (*See* Decision Summary, Ex. A.) Plaintiff's attempt to assert that "Dexcom did not sufficiently warn the user" runs afoul of the requirements and approval FDA set forth. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015) (rejecting plaintiff's failure-to-warn claim because plaintiff offered "no answer to the conundrum how she might impose a state tort duty on [the manufacturer] to revise a label that federal regulation precludes it from revising"). Accordingly, the Court should dismiss plaintiff's failure-to-warn claim as preempted.

c. Plaintiff's Manufacturing Defect Claim Is Preempted

Plaintiff's purported manufacturing defect claim, whether asserted under a strict liability or negligence theory, is expressly preempted. The special controls for the G6 "set[] forth 'requirements' for the design and manufacture of [the G6] that are directed to safety and efficacy," thereby preempting plaintiff's vague allegations that the Dexcom G6 App was somehow defectively manufactured. *See Kelsey*, 2019 WL 1884225, at *10 (dismissing manufacturing defect claim of 510(k) device where on-point FDA Guidance controlled the manufacturing process); *Sharp v. St. Jude Med., S.C., Inc.*, 396 F. Supp. 3d 1250, 1256 (N.D. Ga. 2019) (dismissing manufacturing defect claim as preempted).

d. Plaintiff's Breach of Warranty Claim Is Preempted

Plaintiff also attempts to assert a breach of warranty claim. (Complt., ¶ 46.) Plaintiff essentially alleges that the G6 was not adequately manufactured, designed, or labeled, which, at their core, are allegations that attempt to support claims for manufacturing, design defect, or failure-to-warn and are thus preempted. Plaintiff's warranty claims necessarily depend upon a finding that the device is not safe and effective – a finding that inevitably would conflict with FDA's conclusive determination that the device is safe and effective as designed and manufactured, as evidenced by its grant of the De Novo classification. See *Riegel*, 552 U.S. at 320-21 ("the MDA pre-empt[s] claims of…breach of implied warranty"); *Thomas*, 116 F.

Supp. 3d at 1367 ("Courts have consistently found that state law claims for breach of warranties based on the safety or effectiveness of the device, impose requirements that 'are different from, or in addition to' federal regulations, and thus are preempted."). Therefore, plaintiff's breach of warranty claim should be dismissed as preempted.

B. ALL PLAINTIFF'S CLAIMS ARE IMPLIEDLY PREEMPTED UNDER THE SUPREME COURT'S CONFLICT-PREEMPTION PRINCIPLES

"When a state statute, administrative rule, or common-law cause of action conflicts with a federal statute, it is axiomatic that the state law is without effect." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 894 (2000); *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("it has been settled that state law that conflicts with federal law is 'without effect.'"). The Supreme Court specifically stated that a state common-law action for damages involving a 510(k) cleared device could be impliedly "pre-empted under conflict pre-emption analysis." *Lohr*, 518 U.S. at 503; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) ("[N]either an express pre-emption provision nor a saving clause bars the ordinary working of conflict pre-emption principles."). Federal law preempts state law where it is "not lawful under federal law…to do what state law required." *PLIVA v. Mensing*, 564 U.S. 604, 618 (2011). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620. "[W]hen a party cannot satisfy its state duties without the Federal

Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 624; *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

Indeed, just as federal law prohibited manufacturers from unilaterally changing the design or labeling of drugs without prior FDA review, Dexcom is prohibited from unilaterally modifying or changing the "design, components, method of manufacture, or intended use" of the G6. *See* 21 C.F.R. §807.81(a)(3). Dexcom also is prohibited from making unilateral labeling changes. Plaintiff alleges that "Dexcom did not sufficiently warn the user" that "the G6 App could stop alerting the user to hypoglycemia or stop receiving glucose information from the G6 System." (*Id.*, ¶¶ 40, 43.) Putting aside that such a warning is already in the labeling, it would be impossible for Dexcom "to comply with both [its] state-law duty to change the label [or design] and [its] federal law duty to keep the label [or design] the same" without prior FDA review by making a different warning. *Mensing*, 564 U.S. at 618.21. Therefore, plaintiff's claims also are impliedly preempted under the Supreme Court's conflict ("impossibility") preemption principles.

C. THE COMPLAINT FAILS TO MEET BASIC PLEADING STANDARDS

1. Plaintiff's Claims Are Deficiently Plead

A complaint must set forth "a short and plain statement of the claim showing

that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). Where it does not do so, a defendant may move to dismiss for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Plaintiff's allegations must be sufficiently particular to survive a motion to dismiss. *See Twombly*, 550 U.S. 544; *Iqbal*, 556 U.S. 662. While "detailed factual allegations" are not necessary, "a formulaic recitation of the elements of a cause of action will not do." *Id*. at 555. Here, plaintiff fails to identify a defect and offers only formulaic recitations of her claims; plaintiff merely tracks the elements of claims without offering any required factual support. *See Horsley v. Rivera*, 292 F.3d 695, 700 (11th Cir. 2002). Thus, every claim in the Complaint is insufficiently pled and should be dismissed.

2. Plaintiff Fails to Allege a Design Defect

The basis of a products liability claim, regardless of whether the plaintiff proceeds under *strict* liability or negligence, must be a defect. *See, e.g.*, O.C.G.A. § 51-1-11(b)(1); *Banks v. ICI Ams.*, 264 Ga. 732, 734, 450 S.E.2d 671, 673 (1994); *Miller v. Ford Motor Co.*, 287 Ga. App. 642, 644, 653 S.E.2d 82, 83 (2007). The most plaintiff says is that "[a]mongst other defects the G6 App could stop alerting the user to hypoglycemia or stop receiving glucose information from the G6 System," but that is a warnings criticism that is belied by the actual warnings. (Complt., ¶¶ 40-41; *see also* Ex. D.) In addition to being preempted, plaintiff's failure to identify any alleged design defect is fatal. *See Goodson v. Boston Sci.*

Corp., 2011 WL 6840593, at *4 (N.D. Ga. Dec. 29, 2011) (holding cursory allegations regarding alleged defect insufficient); *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1344-45 (N.D. Ga. 2012) (finding plaintiff failed to state claim and meet pleading standard "because the complaint is silent as to a design or manufacturing defect").

Plaintiff does not even attempt to specify any alleged design defect or any "other defects" in the G6. (Complt., ¶ 40.) Such vague allegations are improper and fail to put Dexcom on notice of any basis for her claims. *See Schmidt v. CR. Bard. Inc.*, 2014 WL 5149175, at *3 (S.D. Ga. Oct. 14, 2014) ("[A] bald assertion that the [device] was defective in design when it left Defendants' hands, was unreasonably dangerous, and the foreseeable risks outweighed the [device's] benefits would be insufficient to survive a motion to dismiss."). Additionally, an alleged injury is insufficient to satisfy plaintiff's pleading requirements. *See Wright*, 741 Fed. Appx. at 626 ("The fact that [plaintiff] experienced pain []… does not inform us how the product was allegedly defective."). Because Plaintiff's allegations are merely a formulaic recitation of design defect elements, plaintiff has not met her burden, and her design defect claim should be dismissed.

3. Plaintiff Fails to Allege a Manufacturing Defect

Plaintiff also fails to allege a single fact to support a manufacturing defect claim. Instead, plaintiff alleges in general and conclusory fashion that "[t]he G6

System and G6 App were…manufactured…and/or sold by Dexcom in a condition which was defective and unreasonably dangerous." (Complt., ¶ 40.) That allegation is wholly inadequate. *See Wright v. Howmedica Osteonics Corp.*, 741 Fed. Appx. 624, 626 (11th Cir. 2018) (dismissing manufacturing defect claim where plaintiff made conclusory statements that product "was defective" or was "unsafe"); *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (affirming dismissal where plaintiff did not "tell [the court] how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process"). Nor can plaintiff simply allege that the device malfunctioned. *See Sharp*, 396 F. Supp. 3d at 1256 (holding complaint fails to allege facts that device suffered from a manufacturing defect as opposed to merely alleging that device malfunctioned"). Plaintiff's manufacturing defect claim is insufficiently plead and should be dismissed.

4. Plaintiff Fails to State a Failure-to-Warn Claim

Plaintiff also does not allege any meaningful facts to support a failure-to-warn claim. Plaintiff contends that "Dexcom did not sufficiently warn the user" that "the G6 App could stop alerting . . . ." (Complt., ¶¶ 40, 43.) However, plaintiff's conclusory statements that Dexcom's warning was "not sufficient," fails to allege "how the substance of the purported warning failed, was otherwise improper, or that [the product's] package contained no warning at all." *Fincher v. Monroe Cty. Bd. of Comm'rs*, 2019 WL 510448, at *8 (M.D. Ga. Feb. 8, 2019) (dismissing warning

claim where plaintiff failed to allege how warning was deficient). In fact, quite to the contrary, FDA issued special controls regarding the G6's labeling, ensuring that Dexcom warned of the potential for "sensor signal drop-out or loss of communication with digitally connected devices." (*See* Ex. A.) And in the User Guide, Dexcom specifically advises of the potential for "signal loss" and the "[d]isplay device and transmitter not connecting." (*See* Ex. D.) Plaintiff cannot assert a warning claim when the User Guide includes the warning plaintiff alleges Dexcom failed to provide. *See Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013) (dismissing claim that was "squarely contradicted by … judicially-noticed drug label that does contains warnings about malignancies").

Not only is plaintiff's failure-to-warn claim insufficiently plead, but it is also contradicted by the User Guide. To plausibly allege a failure-to-warn claim, a plaintiff must "assert[] that the insert was, in fact, improperly labeled and that 'the inadequacy of the warning [label] proximately caused [her] injury.'" *See Wright*, 741 Fed. Appx. at 626. Plaintiff claims that "Dexcom did not sufficiently warn the user" that "the G6 App could stop alerting the user to hypoglycemia or stop receiving glucose information from the G6 System." (Complt., ¶¶ 40, 43.) However, the User Guide for the Dexcom G6 contains warnings for those exact issues.

Specifically, the User Guide includes numerous warnings regarding the potential for "signal loss" and "[d]isplay device and transmitter not connecting."

(*See* G6 User Guide, 36, 145, 231, Ex. D.) In instances of signal loss, users are advised to "No glucose alarm/alerts or G6 readings until fixed. Use meter." (*Id.*, at 227.) Because the User Guide includes the exact warnings plaintiff alleges Dexcom failed to provide, plaintiff has not alleged the G6 warnings were inadequate. *See Chapman*, 930 F. Supp. 2d at 1323.

D. PLAINTIFF'S BREACH OF WARRANTY CLAIM SHOULD BE DISMISSED

Plaintiff alleges that by "designing, developing, manufacturing, promoting, supplying, distributing, selling, and instructing in the use of the G6 system," Dexcom warranted that the G6 was free from defects and was merchantable and reasonably fit for the purpose for which it was intended. (Complt., ¶ 46.) Though it is unclear whether plaintiff is alleging breach of express warranty or implied warranty of merchantability, plaintiff fails to allege facts to support either theory.

To assert a viable implied warranty of merchantability claim, plaintiff must be in privity with the seller. *Butts v. Stryker Corp.*, 2014 WL 12772370, at *4 (S.D. Ga. June 30, 2014). Accordingly, "Georgia courts have repeatedly held that where a plaintiff lacks contractual privity with a manufacturer, he cannot bring an implied warranty claim against that manufacturer." *Gill v. Blue Bird Body Co.*, 147 F. App'x 807, 809-10 (11th Cir. 2005) (collecting cases). The implied warranty can be enforced **only** by the original purchaser against the manufacturer. Plaintiff does not allege that she purchased the G6, nor can she. Accordingly, plaintiff fails to allege

sufficient facts to state a plausible breach of implied warranty of merchantability, and that claim should be dismissed. *See Butts*, 2014 WL 12772370, at *4.

Plaintiff's express warranty claim likewise should be dismissed. To assert a breach of express warranty claim, plaintiff must allege that Dexcom made an affirmation of fact or promise relating to the goods that became the basis of the bargain. *In re Conagra Peanut Butter Prods. Liab. Litig.*, 2011 WL 13118036, at *2 (N.D. Ga. July, 28, 2011). Plaintiff makes no allegations that Dexcom—or anyone—made an affirmation of fact or promise relating to the G6 App or the G6 to Mr. Tuttle. Without such allegations, plaintiff has not alleged sufficient facts to state a plausible breach of express warranty claim. *Id.*, at *2.

E. PLAINTIFF IS NOT ENTITLED TO PUNITIVE DAMAGES

Plaintiff's sole allegation related to punitive damages is that "Dexcom showed willful misconduct, malice, fraud, wantonness, oppression, and that entire want of care which would raise the presumption of conscious indifference to consequences." (Complt. ¶ 52.) There are no facts to support that conclusory allegation. Instead, plaintiff merely recites legal elements without any factual support. Plaintiff's allegations are insufficient as a matter of law. *See, e.g.*, *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1353 (N.D. Ga. 2012).[12]

[12] *See also Henderson v. Sun Pharms. Indus., Ltd.*, 2011 WL 4024656, at *8 (N.D. Ga. June 9, 2011); *Taylor v. MillerCoors, LLC*, 2014 WL 4179918, *1 (M.D. Ga. Aug. 20, 2014) (dismissing punitive damages claim that contained only "a threadbare recital of the elements for such a claim").

Moreover, as a general rule, punitive damages are not available where a defendant complied with relevant regulations and industry standards. *Hernandez v. Crown Equip. Corp.*, 92 F. Supp. 3d 1325, 1356 (M.D. Ga. 2015) (citing *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 2005)). That is because regulatory compliance controverts and undermines the plausibility of unsupported allegations of willful misconduct. *Stone Man*, 435 S.E.2d at 206. FDA reviewed, approved, and cleared the Dexcom G6 for marketing after compliance with carefully and specifically calibrated regulatory controls demonstrating the reasonable assurance of safety and effectiveness. (*See* Ex. A.) There are no factual allegations that Dexcom acted with willful misconduct or conscious indifference. Accordingly, plaintiff's punitive damages count should be dismissed.

IV. CONCLUSION

Plaintiff has not stated any viable claim against Dexcom, Inc. All the claims are preempted by federal law or otherwise fail under Georgia law. Accordingly, Dexcom respectfully requests an order granting this motion and dismissing plaintiff's Complaint with prejudice.

Respectfully submitted,

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CERTIFICATION AS TO FONT

Counsel certifies that this pleading has been prepared in Times New Roman font in 14-point type.

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CERTIFICATE OF SERVICE

I certify that on December 18, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system upon:

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